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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,576	11/08/1999	CHIH-MING CHEN	300.1003	5401

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/435,576	**Applicant(s)** CHEN ET AL.	
	Examiner Sharmila S. Gollamudi	**Art Unit** 1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 April 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *23 November 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

The rejection under 112, first paragraph is withdrawn in view of applicant's arguments.

Applicant argues that Alberts does not teach a similar device. Applicant argues Alberts core does not contain a water-swellable polymer, a seal coat, an inner coating containing an enteric polymer, an outer coating contained an enteric coating and an insoluble polymer. As indicated in the Final Office Action, Table 1 provides the structure, which provides the instant functional limitations. The device provided in Table I only requires a core and an outer coating. The seal coat, an inner coat, and overcoat are not required since the claimed range encompasses zero. Zero clearly implies that the coating is not required. Therefore, examiner points out that the instant structure as defined in Table 1 and that of the prior art are substantially the same used for the same purpose. With regard to the water-soluble polymer, Alberts examples utilize a water-soluble polymer in the core. Therefore, the examiner has made a reasonable rationale for inherency. With regard to McClelland's structure is not similar to Albert's structure as argued by applicant.

Applicant argues that Chen et al does not direct one to specifically select the instant species. Applicant argues that the genus is not sufficiently limited as to render each member inherently disclosed. As discussed in the Final Office Action, the examiner recognizes that HMG-CoA Reductase Inhibitors are suggested and not exemplified. Hence, the examiner makes the rejection under obviousness and as applicant is well aware, in an obviousness rejection, the prior art need only suggest the instant invention. In instant case, Chen is generally directed to a controlled release device for a once-a-day administration for water-insoluble drugs including the instant HMG-CoA Reductase Inhibitors, to increase patient compliance. See column 2, lines 64-65. Although the pharmokinectics of nifendipine are exemplified, a skilled artisan one would

have been motivated to substitute nifendipine with the instant lovastatin and expect similar pharmacokinetic values since Chen clearly suggests the use of other drugs in place of nifedipine. Furthermore, it should be noted that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). The examiner also points out that the rejection is not based on the premise that one would immediately envisage the use of the instant compounds, which is anticipation. The examiner's premise is that it would have been obvious to utilize the instantly claimed compounds as suggested by Chen. With regard to the motivation to select the instant compounds, as set forth in the rejection, Chen specifically states that the statin drugs are suitable for use in the osmotic device.

Applicant argues that Chen does not hint or suggest the Tmax. The examiner points out that the recognition or claiming a property that is implicit in the prior art, which has not been recognized by the prior art, is not a basis for patentability. It is the examiner's position that the instantly claimed Tmax would implicitly flow from the devices taught by Chen for the reasons set forth in the Final Office Action. As set forth in the rejection above, it is the examiner's position that Chen's controlled device would inherently provide the instant Tmax. The rationale is as follows: The examiner points out that Chen teaches a core containing the drug, povidone (a water-swellable polymer), an osmotic agent (lactose), and sodium lauryl sulfate (surfactant) in applicant's amount disclosed in Table I. The core is coated with a color coating containing a dye and sodium chloride (osmotic agent). The prior art's color coat is comparable to applicant's seal coat. Then a sustained release coating containing Eudragit S (enteric polymer), and a plasticizer in applicant amount disclosed in Table I. The prior art's sustained release coat is comparable to

applicant's inner coat. Lastly, the tablet is again coated with an enteric coating polymer containing an enteric polymer, a pore-forming agent (channeling agent), acetyltributyl citrate (plasticizer). The prior art's enteric coat is comparable to applicant's overcoat. Therefore, it can be seen that this device is the same as the described in instant specification of the preferred controlled release device that provides functional limitations of the instant application. Thus, it is the examiner's position that Chen's controlled release device would function similarly. It is pointed out that the examiner has provided a rationale that the prior art would function the same; thus the burden has shifted to applicant to prove otherwise. As noted in *In re Best*, the Patent Office can require the applicant to prove that a subject matter shown in the prior art does not possess a characteristic when there is reason to believe that the functional limitation asserted to be critical in establishing novelty in the claimed subject matter, is possessed by the prior art.

The rejections are maintained for the reasons above.